IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Allen, Keith D.	Examiner:	Sullivan, Daniel M.
Serial No.:	09/900,754	Group Art Unit:	1636
Filed:	July 6, 2001	Docket No.:	R-372/75658.031700
Title:	Transgenic Mice Containing Tryptase Gene Disruptions		

DECLARATION OF JOHN BURKE PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, John E. Burke, residing at 16357 E. Berry Avenue, Centennial CO 80015, hereby declare:

1. I am currently, and have been since 1998, the Attorney of Record for the Applicant and Assignee, Deltagen, Inc. I am listed on the originally filed Power of Attorney for the present application. From December 1996 to December 1999, I was Of Counsel with the law firm of Pillsbury Madison & Sutro (currently Pillsbury Winthrop) where I represented Deltagen with respect to intellectual property matters, including patent matters relating to their transgenic mouse program. From December 1999 until December 2001, I served as Deltagen's Vice President of Intellectual Property, where I supervised Deltagen's internal patent department. All of the applications, including the present application, covering the 750 lines of mice in DeltaBase were drafted by Deltagen's patent department. From December 2001 until April 2003, I served as Deltagen's Senior Vice President and General Counsel. From April 2003 through April 2005, I was a partner with the Denver office of Merchant & Gould, where I continued to represent Deltagen with regard to intellectual matters, including patent matters. I am presently employed as a Shareholder with the Denver office of the law firm of Greenberg Traurig, where I am

responsible for prosecution of Deltagen's patent portfolio relating to their transgenic mice program, including the present application.

2. I am familiar with the present application. I am familiar with the Office Action mailed May 12, 2005. I am aware that the Examiner has rejected the claims, in part, for allegedly failing to meet the utility and enablement requirements. I am aware that the Examiner has argued that the phenotypic differences observed in the transmembrane tryptase (mTMT) gene knockout mouse are not statistically significant.

3. I hereby declare that, as evidenced by the attached Exhibit, the subject matter of the present application, mTMT gene knockout mice, were compared with control mice of identical background. I further declare that when compared to such control mice, the mTMT gene knockout mice exhibit statistically significant phenotypic differences.

4. I hereby declare that the claimed mTMT gene knockout mouse has been extensively analyzed using the tests set forth in the Examples. This data has been incorporated into Deltagen's commercial database product, DeltaBase. This database has been subscribed to by at least three of the world's largest pharmaceutical companies, Merck, Pfizer and GSK.

5. I hereby declare that I have accessed Deltagen's internal web-based DeltaBase database to review the data derived from analyses of the claimed mice. I hereby declare that the attached Exhibit contains 4 pages, each representing a screen printout from DeltaBase. Pages 1-2 (a single web page that has been printed on two separate pages) describe the behavioral phenotypes for mTMT knockout mice (the printout refers to Gene 372 which is Deltagen's internal code for the mTMT gene, as indicated in the docket number of the instant case. The printout also refers to the gene as Tpsg1 which is a synonym for mTMT). Pages 1-2 also describe how the mTMT knockout mice were generated. Specifically, pages 1-2 state that ES cells derived from the 129/SvJ x 129/Sv-+p+Tyr-c MgfSl-J/+ mouse substrain were used to generate chimeric mice. F1 mice were generated by breeding with C57BL/6 females. The resultant F1N0 heterozygotes were backcrossed to C57BL/6 mice to generate F1N1 heterozygotes. F2N1 homozygous mutant mice were produced by intercrossing F1N1 heterozygous males and females. Pages 1-2 also states that when compared to age-and gender-matched wild-type control mice, homozygous mutants mice displayed a difference in Prepulse

Inhibition (PPI), indicating a stimulus processing phenotype opposite to that seen in schizophrenic patients. Pages 1-2 also indicate the genotype of the -/- and +/+ wild-type control mice (table on right hand side of pages 1-2). It can be seen that all -/- and +/+ mice tested were F2N1 mice, *i.e.* the control mice were the wild-type progeny, and the mutant mice were the homozygous -/- progeny, of crosses between male and female mice heterozygous for the mTMT null allele.

Page 3 presents the PPI findings in more detail, and also shows that the data were compiled from the F2N1 generations (data from one F2N0 mouse was subsequently excluded). All mice (wild-type, -/+, and -/-) were derived from the same ES cell line, 479. The ages and gender of the mouse are also indicated. Thus, the printout shows that -/- , -/+ and +/+ mice of the same strain (background), same F number, same N number, same gender, and same age were compared in the PPI test.

Page 4 presents the PPI results for the eleven -/- mice and the nine wild-type control mice of page 3. Page 4 also provides the 1-*p* values for the differences between the wild-type control and -/- mice. It can be seen that for the PPI measured captioned "PPI 90/120" (the % reduction in the startle response to a 120dB stimulus that is observed with a 90dB prepulse), the difference between wild-type control and -/- mice is highly statistically significant, with a 1-*p* value of 0.98.

6. In summary, the attached Exhibits show that the -/- mice were compared with control mice of identical age, gender, and background (strain) in the PPI test. The attached Exhibits also show that the difference between the PPI 90/120 results for -/- mice and +/+ mice is statistically significant.

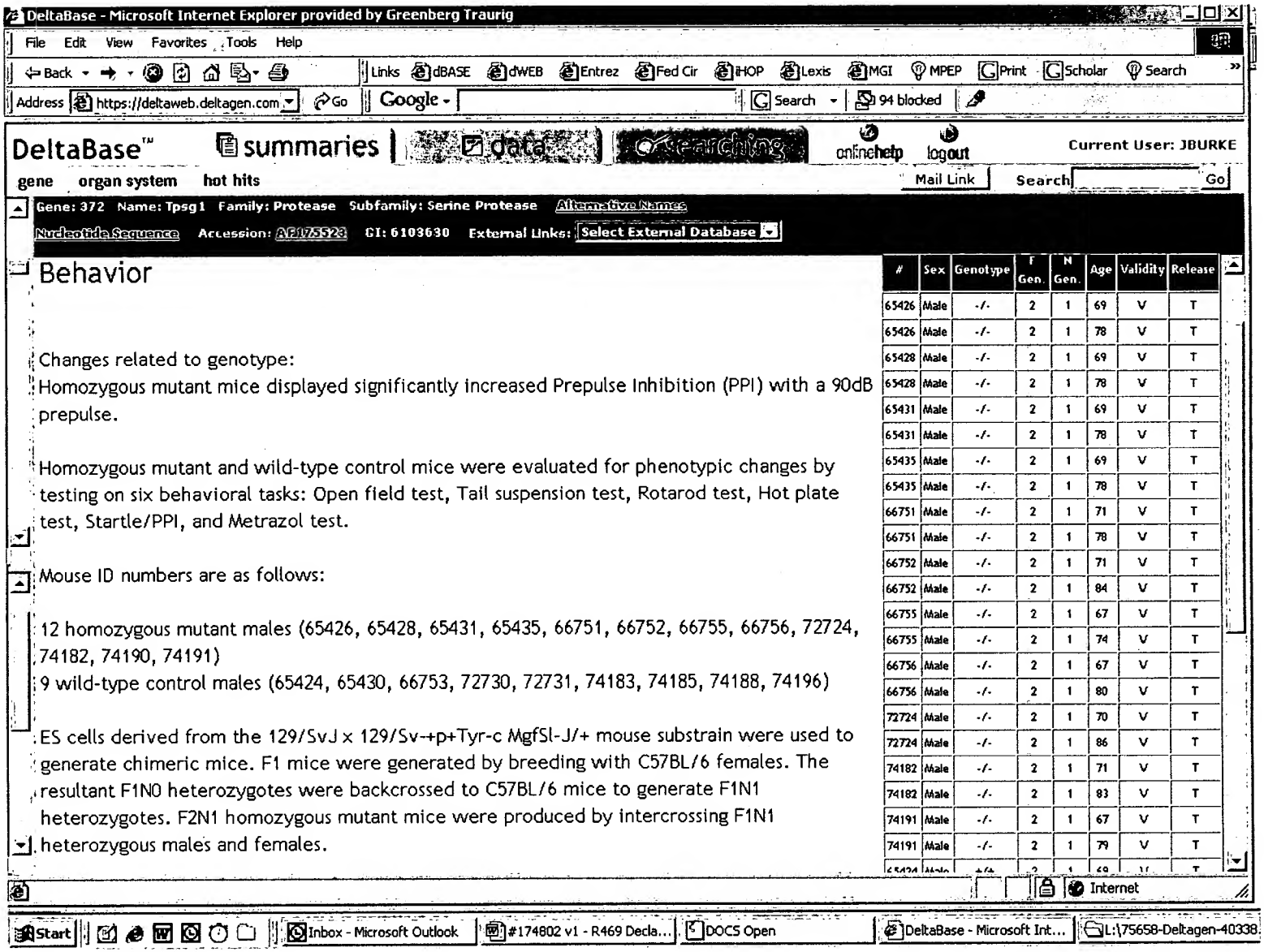
7. I further declare that all statements made herein of my own knowledge are true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

JER

John E. Burke, Reg. No. 35,836

8-24-05

Date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Gene: 372 Name: Tpsg1 Family: Protease Subfamily: Serine Protease Alternative Names
Nucleotide Sequence Accession: AF175523 GI: 6103630 External Links: Select External Database
Behavior
Changes related to genotype:
Homozygous mutant mice displayed significantly increased Prepulse Inhibition (PPI) with a 90dB prepulse.
Homozygous mutant and wild-type control mice were evaluated for phenotypic changes by testing on six behavioral tasks: Open field test, Tail suspension test, Rotarod test, Hot plate test, Startle/PPI, and Metrazol test.
Mouse ID numbers are as follows:
12 homozygous mutant males (65426, 65428, 65431, 65435, 66751, 66752, 66755, 66756, 72724, 74182, 74190, 74191)
9 wild-type control males (65424, 65430, 66753, 72730, 72731, 74183, 74185, 74188, 74196)
ES cells derived from the 129/SvJ x 129/Sv-+p+Tyr-c MgfSl-J/+ mouse substrain were used to generate chimeric mice. F1 mice were generated by breeding with C57BL/6 females. The resultant F1N0 heterozygotes were backcrossed to C57BL/6 mice to generate F1N1 heterozygotes. F2N1 homozygous mutant mice were produced by intercrossing F1N1 heterozygous males and females.
Sex Genotype F Gen. N Gen. Age Validity Release
65426 Male -/- 2 1 69 V T
65426 Male -/- 2 1 78 V T
65428 Male -/- 2 1 69 V T
65428 Male -/- 2 1 78 V T
65431 Male -/- 2 1 69 V T
65431 Male -/- 2 1 78 V T
65435 Male -/- 2 1 69 V T
65435 Male -/- 2 1 78 V T
66751 Male -/- 2 1 71 V T
66751 Male -/- 2 1 78 V T
66752 Male -/- 2 1 71 V T
66752 Male -/- 2 1 84 V T
66755 Male -/- 2 1 67 V T
66755 Male -/- 2 1 74 V T
66756 Male -/- 2 1 67 V T
66756 Male -/- 2 1 80 V T
72724 Male -/- 2 1 70 V T
72724 Male -/- 2 1 86 V T
74182 Male -/- 2 1 71 V T
74182 Male -/- 2 1 83 V T
74191 Male -/- 2 1 67 V T
74191 Male -/- 2 1 79 V T
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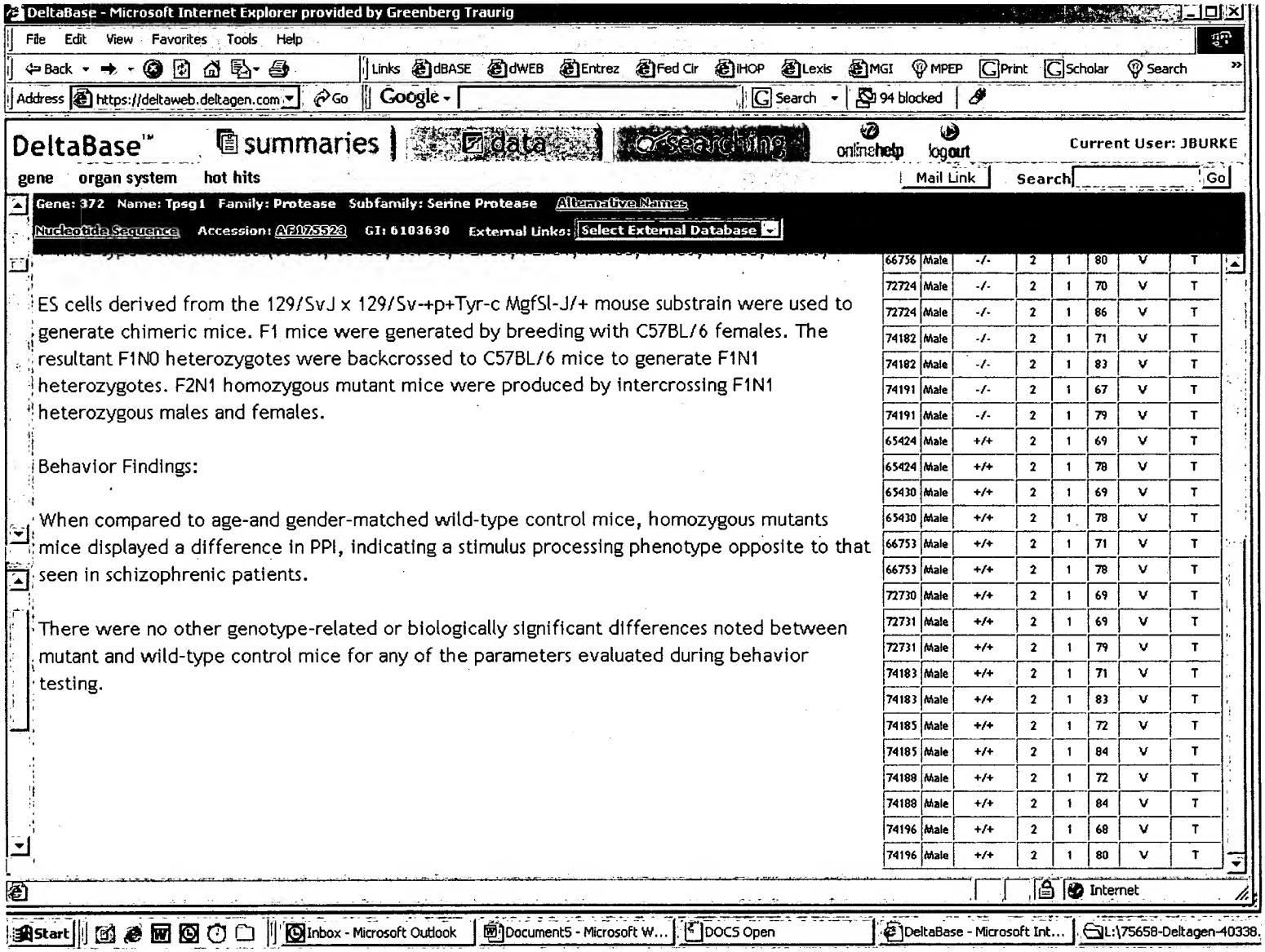
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gene organ system hot hits Mail Link Search Go
Gene: 372 Name: Tpsg1 Family: Protease Subfamily: Serine Protease Alternative Names
Nucleotide Sequence Accession: AF175523 GI: 6103630 External Links: Select External Database
ES cells derived from the 129/SvJ x 129/Sv-+p+Tyr-c MgfSl-J/+ mouse substrain were used to generate chimeric mice. F1 mice were generated by breeding with C57BL/6 females. The resultant F1N0 heterozygotes were backcrossed to C57BL/6 mice to generate F1N1 heterozygotes. F2N1 homozygous mutant mice were produced by intercrossing F1N1 heterozygous males and females.
Behavior Findings:
When compared to age-and gender-matched wild-type control mice, homozygous mutants mice displayed a difference in PPI, indicating a stimulus processing phenotype opposite to that seen in schizophrenic patients.
There were no other genotype-related or biologically significant differences noted between mutant and wild-type control mice for any of the parameters evaluated during behavior testing.
66756 Male -/- 2 1 80 V T
72724 Male -/- 2 1 70 V T
72724 Male -/- 2 1 86 V T
74182 Male -/- 2 1 71 V T
74182 Male -/- 2 1 83 V T
74191 Male -/- 2 1 67 V T
74191 Male -/- 2 1 79 V T
65424 Male +/+ 2 1 69 V T
65424 Male +/+ 2 1 78 V T
65430 Male +/+ 2 1 69 V T
65430 Male +/+ 2 1 78 V T
66753 Male +/+ 2 1 71 V T
66753 Male +/+ 2 1 78 V T
72730 Male +/+ 2 1 69 V T
72731 Male +/+ 2 1 69 V T
72731 Male +/+ 2 1 79 V T
74183 Male +/+ 2 1 71 V T
74183 Male +/+ 2 1 83 V T
74185 Male +/+ 2 1 72 V T
74185 Male +/+ 2 1 84 V T
74188 Male +/+ 2 1 72 V T
74188 Male +/+ 2 1 84 V T
74196 Male +/+ 2 1 68 V T
74196 Male +/+ 2 1 80 V T
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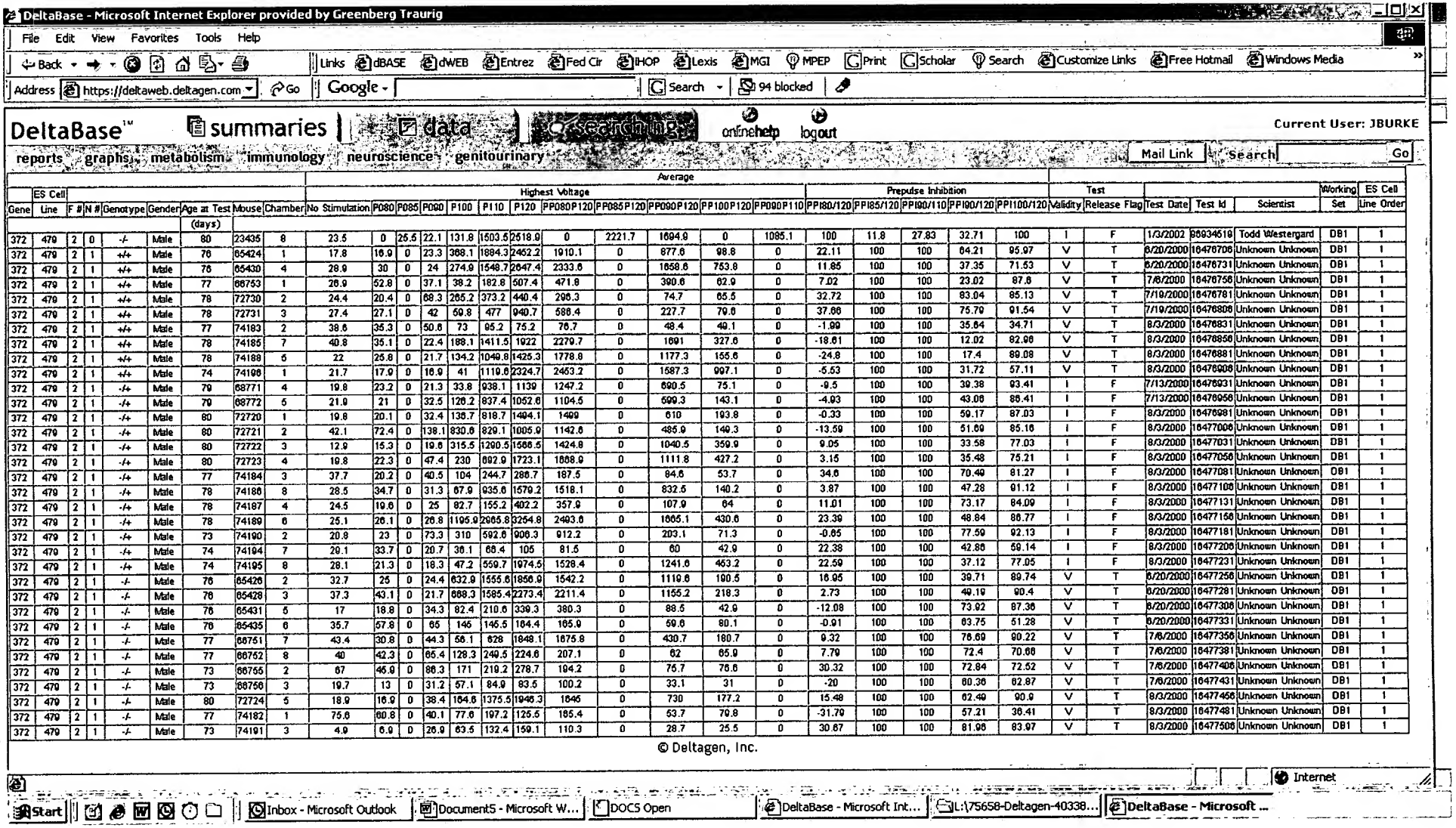

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									Average																												
	ES Cell								Highest Voltage											Prepulse Inhibition					Test							Working	ES Cell
Gene	Line	F #	N #	Genotype	Gender	Age at Test (days)	Mouse	Chamber	No Stimulation	P080	P085	P090	P100	P110	P120	PP080P120	PP085P120	PP090P120	PP100P120	PP090P110	PPI80/120	PPI85/120	PPI90/110	PPI90/120	PPI100/120	Validity	Release Flag	Test Date	Test Id	Scientist	Set	Line Order
372	479	2	0	-/-	Male	80	23435	8	23.5	0	25.5	22.1	131.8	1503.5	2518.9	0	2221.7	1694.9	0	1085.1	100	11.8	27.83	32.71	100	I	F	1/3/2002	86934619	Todd Westergard	DB1	1
372	479	2	1	+/+	Male	76	65424	1	17.8	16.9	0	23.3	368.1	1884.3	2452.2	1910.1	0	877.6	98.8	0	22.11	100	100	64.21	95.97	V	T	6/20/2000	16476706	Unknown Unknown	DB1	1
372	479	2	1	+/+	Male	76	65430	4	28.9	30	0	24	274.9	1548.7	2647.4	2333.6	0	1658.6	753.8	0	11.85	100	100	37.35	71.53	V	T	6/20/2000	16476731	Unknown Unknown	DB1	1
372	479	2	1	+/+	Male	77	66753	1	26.9	52.8	0	37.1	38.2	182.8	507.4	471.8	0	390.6	62.9	0	7.02	100	100	23.02	87.8	V	T	7/6/2000	16476756	Unknown Unknown	DB1	1
372	479	2	1	+/+	Male	78	72730	2	24.4	20.4	0	68.3	265.2	373.2	440.4	296.3	0	74.7	65.5	0	32.72	100	100	83.04	85.13	V	T	7/19/2000	16476781	Unknown Unknown	DB1	1
372	479	2	1	+/+	Male	78	72731	3	27.4	27.1	0	42	59.8	477	940.7	586.4	0	227.7	79.6	0	37.66	100	100	75.79	91.54	V	T	7/19/2000	16476806	Unknown Unknown	DB1	1
372	479	2	1	+/+	Male	77	74183	2	38.6	35.3	0	50.6	73	95.2	75.2	76.7	0	48.4	49.1	0	-1.99	100	100	35.64	34.71	V	T	8/3/2000	16476831	Unknown Unknown	DB1	1
372	479	2	1	+/+	Male	78	74185	7	40.8	35.1	0	22.4	188.1	1411.5	1922	2279.7	0	1691	327.6	0	-18.61	100	100	12.02	82.96	V	T	8/3/2000	16476856	Unknown Unknown	DB1	1
372	479	2	1	+/+	Male	78	74188	6	22	25.8	0	21.7	134.2	1049.8	1425.3	1778.8	0	1177.3	155.6	0	-24.8	100	100	17.4	89.08	V	T	8/3/2000	16476881	Unknown Unknown	DB1	1
372	479	2	1	+/+	Male	74	74196	1	21.7	17.9	0	16.9	41	1119.6	2324.7	2463.2	0	1587.3	997.1	0	-5.53	100	100	31.72	57.11	V	T	8/3/2000	16476906	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	79	68771	4	19.8	23.2	0	21.3	33.8	938.1	1139	1247.2	0	690.5	75.1	0	-9.5	100	100	39.38	93.41	I	F	7/13/2000	16476931	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	79	68772	5	21.9	21	0	32.5	126.2	837.4	1052.6	1104.6	0	599.3	143.1	0	-4.93	100	100	43.06	86.41	I	F	7/13/2000	16476956	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	80	72720	1	19.8	20.1	0	32.4	136.7	818.7	1404.1	1499	0	610	193.8	0	-0.33	100	100	59.17	87.03	I	F	8/3/2000	16476981	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	80	72721	2	42.1	72.4	0	138.1	830.6	829.1	1005.9	1142.6	0	485.9	149.3	0	-13.59	100	100	51.69	85.16	I	F	8/3/2000	16477006	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	80	72722	3	12.9	15.3	0	19.6	315.5	1290.5	1566.5	1424.8	0	1040.5	359.9	0	9.05	100	100	33.58	77.03	I	F	8/3/2000	16477031	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	80	72723	4	19.8	22.3	0	47.4	230	892.9	1723.1	1688.9	0	1111.8	427.2	0	3.15	100	100	35.48	75.21	I	F	8/3/2000	16477056	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	77	74184	3	37.7	20.2	0	40.5	104	244.7	286.7	187.5	0	84.6	53.7	0	34.6	100	100	70.49	81.27	I	F	8/3/2000	16477081	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	78	74186	8	28.5	34.7	0	31.3	67.9	935.6	1579.2	1518.1	0	832.5	140.2	0	3.87	100	100	47.28	91.12	I	F	8/3/2000	16477106	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	78	74187	4	24.5	19.6	0	25	82.7	155.2	402.2	357.9	0	107.9	64	0	11.01	100	100	73.17	84.09	I	F	8/3/2000	16477131	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	78	74189	6	25.1	26.1	0	26.8	1195.9	2965.8	3254.8	2493.6	0	1665.1	430.6	0	23.39	100	100	48.84	86.77	I	F	8/3/2000	16477156	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	73	74190	2	20.8	23	0	73.3	310	592.6	906.3	912.2	0	203.1	71.3	0	-0.65	100	100	77.59	92.13	I	F	8/3/2000	16477181	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	74	74194	7	29.1	33.7	0	20.7	36.1	66.4	105	81.5	0	60	42.9	0	22.38	100	100	42.86	59.14	I	F	8/3/2000	16477206	Unknown Unknown	DB1	1
372	479	2	1	-/+	Male	74	74195	8	28.1	21.3	0	18.3	47.2	559.7	1974.5	1528.4	0	1241.6	463.2	0	22.59	100	100	37.12	77.05	I	F	8/3/2000	16477231	Unknown Unknown	DB1	1
372	479	2	1	-/-	Male	76	65426	2	32.7	25	0	24.4	632.9	1555.6	1856.9	1542.2	0	1119.6	190.5	0	16.95	100	100	39.71	89.74	V	T	6/20/2000	16477256	Unknown Unknown	DB1	1
372	479	2	1	-/-	Male	76	65428	3	37.3	43.1	0	21.7	668.3	1585.4	2273.4	2211.4	0	1155.2	218.3	0	2.73	100	100	49.19	90.4	V	T	6/20/2000	16477281	Unknown Unknown	DB1	1
372	479	2	1	-/-	Male	76	65431	5	17	18.8	0	34.3	82.4	210.6	339.3	380.3	0	88.5	42.9	0	-12.08	100	100	73.92	87.36	V	T	6/20/2000	16477306	Unknown Unknown	DB1	1
372	479	2	1	-/-	Male	76	65435	6	35.7	57.8	0	65	146	146.5	164.4	165.9	0	59.6	80.1	0	-0.91	100	100	63.75	51.28	V	T	6/20/2000	16477331	Unknown Unknown	DB1	1
372	479	2	1	-/-	Male	77	66751	7	43.4	30.8	0	44.3	56.1	628	1848.1	1675.8	0	430.7	180.7	0	9.32	100	100	76.69	90.22	V	T	7/6/2000	16477356	Unknown Unknown	DB1	1
372	479	2	1	-/-	Male	77	66752	8	40	42.3	0	66.4	128.3	249.5	224.6	207.1	0	62	65.9	0	7.79	100	100	72.4	70.66	V	T	7/6/2000	16477381	Unknown Unknown	DB1	1
372	479	2	1	-/-	Male	73	66755	2	67	46.9	0	86.3	171	219.2	278.7	194.2	0	75.7	75.6	0	30.32	100	100	72.84	72.52	V	T	7/6/2000	16477406	Unknown Unknown	DB1	1
372	479	2	1	-/-	Male	73	66756	3	19.7	13	0	31.2	57.1	84.9	83.5	100.2	0	33.1	31	0	-20	100	100	60.36	62.87	V	T	7/6/2000	16477431	Unknown Unknown	DB1	1
372	479	2	1	-/-	Male	80	72724	5	18.9	16.9	0	38.4	164.6	1375.5	1946.3	1646	0	730	177.2	0	15.48	100	100	62.49	90.9	V	T	8/3/2000	16477456	Unknown Unknown	DB1	1
372	479	2	1	-/-	Male	77	74182	1	75.6	60.8	0	40.1	77.6	197.2	125.5	185.4	0	53.7	79.8	0	-31.79	100	100	57.21	36.41	V	T	8/3/2000	16477481	Unknown Unknown	DB1	1
372	479	2	1	-/-	Male	73	74191	3	4.9	6.9	0	26.9	63.5	132.4	159.1	110.3	0	28.7	25.5	0	30.87	100	100	81.96	83.97	V	T	8/3/2000	16477506	Unknown Unknown	DB1	1

Internet

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Phenotypic Data - Startle - - Microsoft Internet Explorer provided by Greenberg Traurig

Address https://deltabase.deltagen.com

View: View/Sort

Startle

Filter: Find - Find All

-- Select Filter --

Related Data: <shift> or <ctrl> click to select row(s)

-- Select Screen --

Phenotypic Data - Startle (Highlight outliers when: wt control relativeDiff value < 1/2 Or 2 < value) 11 Records - 1 Page - <20 records/page

F #	Age at Test (days)	Mouse	Chamber	Average: Highest Voltage: No Stimulation	P080	P085	P090	P100	P110	P120	PP080P120	PP085P120	PP090P120	PP100P120	PP090P110	Prepulse Inhibition: PPI80/120	PPI85/120	PPI90/110	PPI90/120	PPI100/120	Test Date
Gene: 372 Protease (Serine Protease): Tpsg1 (Accession) ES Cell Line: 479																					
N #: 1 Genotype: -/- Gender: Male																					
2	76	65426	2	32.7	25	0	24.4	632.9	1555.6	1856.9	1542.2	0	1119.6	190.5	0	16.95	100	100	39.71	89.74	6/20/2000
2	76	65428	3	37.3	43.1	0	21.7	668.3	1585.4	2273.4	2211.4	0	1155.2	218.3	0	2.73	100	100	49.19	90.4	6/20/2000
2	76	65431	5	17	18.8	0	34.3	82.4	210.6	339.3	380.3	0	88.5	42.9	0	-12.08	100	100	73.92	87.36	6/20/2000
2	76	65435	6	35.7	57.8	0	65	145	145.5	164.4	165.9	0	59.6	80.1	0	-0.91	100	100	63.75	51.28	6/20/2000
2	77	66751	7	43.4	30.8	0	44.3	56.1	628	1848.1	1675.8	0	430.7	180.7	0	9.32	100	100	76.69	90.22	7/6/2000
2	77	66752	8	40	42.3	0	65.4	128.3	249.5	224.6	207.1	0	62	65.9	0	7.79	100	100	72.4	70.66	7/6/2000
2	73	66755	2	67	45.9	0	86.3	171	219.2	278.7	194.2	0	75.7	76.6	0	30.32	100	100	72.84	72.52	7/6/2000
2	73	66756	3	19.7	13	0	31.2	57.1	84.9	83.5	100.2	0	33.1	31	0	-20	100	100	60.36	62.87	7/6/2000
2	80	72724	5	18.9	16.9	0	38.4	164.6	1375.5	1946.3	1645	0	730	177.2	0	15.48	100	100	62.49	90.9	8/3/2000
2	77	74182	1	75.6	60.8	0	40.1	77.6	197.2	125.5	165.4	0	53.7	79.8	0	-31.79	100	100	57.21	36.41	8/3/2000
2	73	74191	3	4.9	6.9	0	26.9	63.5	132.4	159.1	110.3	0	28.7	25.5	0	30.67	100	100	81.96	83.97	8/3/2000
			Average	35.65	32.85	0.	43.45	204.25	580.35	845.44	763.44	0.	348.8	106.23	0.	4.41	100.	100.	64.59	75.12	
			Std. Dev.	21.21	18.31	0.	20.4	224.8	612.73	909.72	816.95	0.	446.53	70.93	0.	19.71	0.	0.	12.64	18.43	
			WT Control Average (9)	27.61	29.03	0.	34.03	160.28	904.68	1415.03	1354.07	0.	859.24	287.78	0.	6.71	100.	100.	42.24	77.29	
			WT Control Std. Dev.	7.66	11.19	0.	17.02	120.23	646.17	966.5	976.74	0.	694.06	349.17	0.	21.67	0.	0.	25.86	19.83	
			1-p	0.7	0.41	0.	0.72	0.4	0.73	0.81	0.84	0.	0.94	0.89	0.	0.19	0.	0.	0.98	0.2	

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